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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,674	03/30/2004	Ulrika Andersson	Strom. 7553	8291

7590 01/04/2005

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,674	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Lora E Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Specification

Applicant is reminded of the proper content, language and format of an abstract of the disclosure.

A patent abstract is a **concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains**. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract **should not refer to purported merits or speculative applications of the invention** and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in **narrative form** and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied**, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The standard for patentability in the area of **living organisms** and biomolecules is whether the claimed matter "is the result of human intervention." See M.P.E.P. § 2105.

Claim 1 is drawn to a mutant of *L. lactis* spp. *lactis*. While specific properties of the claimed mutant are recited, the claim does not disclose any isolation or purification step that necessarily involves the hand of man.

Claims 3, 4 and 13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically *L. lactis* spp. *lactis* 19435, DSM 14489 and TMB5003. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited TMB5003 (p.5, lines 8-11), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that

the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a mutant of *L. lactis* spp. *lactis* having several characteristics with regard to lactate and lactate dehydrogenase production and various uses for said mutant. Claim 1 is further indefinite in that it compares the production of lactate and lactate dehydrogenase by the claimed mutant to that by another strain, but it provides no specific conditions under which said comparison could be made, or indeed whether the claimed strain and the 19435 strain were grown under identical conditions for the recited comparison. Clarification is required.

Claims 3, 4 and 13 provide for the use of *L. lactis* spp. *lactis* TMB5003, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 recites "preferred" conditions, which do not precisely define the metes and bounds of the claims. Specifically, claim 4 recites use of a bacterium for the production of lactate dehydrogenase (LDH), **in particular** L-lactate dehydrogenase (L-LDH). The phrase "in particular" has been interpreted to mean "preferably." It is not clear whether this claim is drawn to the production of LDH, L-LDH, or both. Clarification is required.

Claims 5-12 are incomplete in the absence of a recovery step for the product produced. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, claim 5 fails to particularly point out and distinctly claim the **complete** process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated. Since claims 6-12 depend from claim 5 and do not clarify the point of indefiniteness, these claims must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 11 and 12 recite "preferred" temperature and pH conditions, which do not precisely define the metes and bounds of the claims. It is not clear whether any conditions other than the recited conditions are part of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' strain differs and, if so, to what extent from the strains discussed in the references. Accordingly, it has been established that the prior art strains, which have the same genus and species classification and share the property of being able to produce lactate and lactate dehydrogenase, demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known strain is not disclosed in a reference does not make the known strain patentable. The known strain possesses inherent characteristics which might not be displayed in the tests used the reference. However, the microbes disclosed by the prior art might be the same microbe as that claimed. Clear evidence that the strains of the cited prior art do not possess a critical characteristic that is possessed by the claimed strain, would advance prosecution and might permit allowance of claims to applicants' strain.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sjoberg et al. (1995, AI on 3/30/04 IDS) in light of Picataggio et al. (1997, WO 97/13842; AG on

3/30/04 IDS). The claims are directed to a mutant of *L. lactis* spp. *lactis* that produces lactate and lactate dehydrogenase at high levels compared to *L. lactis* spp. *lactis* 19435. In some dependent claims, the mutant is denoted TMB5003. Some dependent claims recite a method for producing lactate comprising cultivating TMB5003. In some dependent claims, TMB5003 is grown in a glucose-containing medium at specific pH and temperature conditions and with specific rates of glucose addition. Some dependent claims recite intended uses for the lactate or lactate dehydrogenase produced by TMB2003.

Sjoberg et al. disclose *L. lactis* spp. *lactis* AS 211, which exhibits increased production of lactate compared to *L. lactis* spp. *lactis* 19435 (Figure 2). Sjoberg et al. also disclose that L-lactate dehydrogenase (LDH) catalyzes the formation of L-lactate from pyruvate; therefore, a strain producing increased lactate must also produce increased lactate dehydrogenase (Figure 1). The medium of Sjoberg et al. comprises unlimited glucose fed at a dilution rate ranging from 0.60-0.85 (Figure 2B). The incubations of Sjoberg et al. were carried out at 30°C (p.932, column 1). WO '842 is cited as evidence that lactate is useful in many fields, including medicine and food processing (p.1, lines 16-17).

No claims are allowed. No claims are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

SANDRA E. SAUCIER
PRIMARY EXAMINER